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| 10/564,902 | 06/15/2006 | William Patrick Hems | JMYS-140US | 3231 |
| 23122 | 7590 | 02/02/2009 | EXAMINER | |
| RATNERPRESTIA | | | KOSACK, JOSEPH R | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/564,902 | Applicant(s) HEMS ET AL. | |
| | Examiner Joseph R. Kosack | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,19 and 20 is/are rejected.
- 7) ☒ Claim(s) 10-18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>1/8/07 & 10/29/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1 and 3-20 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1 and 3-18) along with an election of species in the reply filed on October 21, 2008 is acknowledged. The search has been expanded to encompass the entire scope of the group as well as non-elected claims 19 and 20. Therefore, the lack of unity requirement made on August 27, 2008 is withdrawn.

Priority

The claim to priority as a 371 filing of PCT/GB04/02938 filed on July 7, 2004, which claims benefit of UK 0316439.9 filed on July 15, 2003 is acknowledged in the instant application.

Information Disclosure Statement

The Information Disclosure Statements filed on January 8, 2007 and October 29, 2007 have been considered by the Examiner.

Claim Objections

Claims 4, 6, 11-13, 17, and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The claims that are objected to are drawn to compounds of Formula I where R1-R8 can connect with other R groups or the A group to form a ring structure. However,

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the base claim does not cover where the substituents may join together to form a ring structure.

Claims 10-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

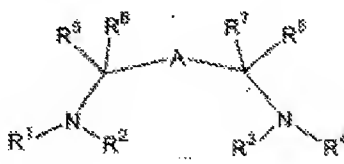
Claims 1, 3-9, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for catalysts with diamines where A and/or B consist of one or two substituted or unsubstituted carbon atoms, does not reasonably provide enablement for catalysts with diamines where A and/or B comprise one or two substituted or unsubstituted carbon atoms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

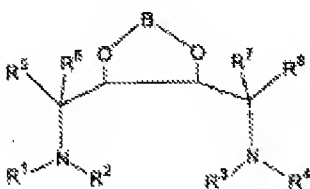
In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention is a catalyst comprising a ruthenium compound, a

chiral bis(phosphine), and a diamine of Formula I  or Formula

II  where A and B are defined as a linking group comprising one or two substituted or unsubstituted carbon atoms. Also claimed is a method of using the catalysts.

The State of the Prior Art and the Predictability or Lack Thereof in the Art

As stated by the Applicant in the specification, the prior art is drawn to numerous examples of using 1,2-diamines as catalysts for asymmetric hydrogenation, but none for other diamines such as 1,3-diamines, 1,4-diamines, 1,5-diamines, etc... The Examiner was unable to uncover any additional art as to asymmetric hydrogenation catalysts with diamines other than 1,2-diamines. Therefore, there is no guidance as to whether diamines with the amine groups farther apart would work or not.

The Amount of Direction or Guidance Present and the Presence or Absence of Working

Examples

The specification details examples of 1,3-diamines and 1,4-diamines in which the linking group consists of one or two carbon atoms to work for this system, but not for any other linking group such as a five atom chain for A or B in which the chain contains

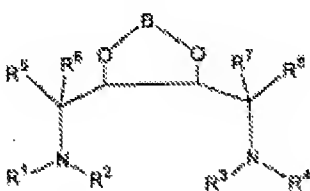
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four carbon atoms and one oxygen atom. Additionally, there is no guidance on how to make compounds of Formula II where B is other than a one or two carbon linking group.

The Breadth of the Claims

The breadth of the claims is a catalyst comprising a ruthenium compound, a

chiral bis(phosphine), and a diamine of Formula I  or Formula

II  where A and B are defined as a linking group comprising one or two substituted or unsubstituted carbon atoms. Also claimed is a method of using the catalysts.

The term "comprising" is open language. Therefore, the term "comprising one or two carbon atoms" would be satisfied, for example, by a ten carbon atom chain since it has at least one or two carbon atoms. The term would also be satisfied by a chain that contains heteroatoms, such as oxygen, nitrogen, and sulfur, as long as the chain contains at least one or two carbon atoms.

The Quantity of Experimentation Needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine all of the reagents, reaction conditions and synthetic schemes in order to make and use the non-enabled claimed compounds. The lack of

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predictability in the art to make a new compound as described above additionally supports a finding of undue experimentation.

The Level of Skill in the Art

The level of skill in the art of organic synthesis and pharmaceuticals is high. However, due to the unpredictability in the art as described above, one of ordinary skill would be unable to make or use the claimed compound without undue experimentation in order to practice the invention as claimed.

Thus, the specification fails to provide sufficient support of the preparation and use of catalysts with diamines where A and/or B comprise one or two substituted or unsubstituted carbon atoms. As a result, the application would require one of skill to perform an exhaustive search and an inordinate number of experiments in order to make or use the claimed compound.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

Conclusion

Claims 1, 3-9, 19, and 20 are rejected. Claims 4, 6, and 10-18 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/
Examiner, Art Unit 1626